

Editorial

Percutaneous coronary intervention: obtaining consent and preparing patients for follow-on procedures

In *Seeking patients' consent: the ethical considerations*, the General Medical Council (GMC) has issued clear guidance on the issue of obtaining consent.¹ In the past it has often been the case that junior medical staff with little or no experience of cardiac catheterisation have obtained consent for both diagnostic coronary angiography and percutaneous coronary intervention (PCI). This is no longer acceptable. The GMC guidelines do allow delegation of the task of obtaining consent to a "suitably trained and qualified person who has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved". However, periprocedural sedation and anxiety preclude obtaining valid consent for a follow-on PCI immediately after the angiogram.² Therefore, follow-on PCI requires that consent be obtained by either a consultant interventional cardiologist or a suitably experienced trainee (usually a specialist registrar) before the diagnostic procedure is performed.

Who should be consented for follow-on intervention?

In the context of an urgent or emergency diagnostic procedure in a patient with an acute coronary syndrome, consent should always be obtained for both angiography and intervention, as it is routine practice to follow-on when indicated. However, even in patients with stable angina undergoing elective investigation there are significant advantages associated with follow-on intervention including reduced procedural costs, and, at least in the UK, avoidance of the risks associated with going on to a waiting list.³ In order to pursue a strategy of follow-on PCI in these patients, it is necessary to prepare and consent all potential candidates in advance of the diagnostic procedure. Non-invasive testing cannot accurately predict the coronary anatomy and cannot in any event indicate whether the pattern of disease will be technically suitable for percutaneous revascularisation. If it is, then in many patients with single and multivessel disease and preserved ventricular function, the decision between surgery and PCI is largely down to patient preference given the similar long term results of both approaches. Accordingly, we have adopted a policy of consenting all patients undergoing elective coronary angiography for follow-on intervention.

What the patient wants and needs to know?

In studies of informed consent in New Zealand it has been shown that, in order of priority, patients want to know the major risks of the procedure, implications for quality and quantity of life, and the outcome of proceeding or not proceeding.⁴ In medico-legal terms the essential requirements for obtaining informed consent are disclosure (of potential risks and benefits), understanding, competence, autonomy, and authorisation.⁵ In practice, before going on to the waiting list for angiography/intervention, the patient should be advised of the incidence of all serious risks associated with both procedures—that is, death, myocardial infarction, and stroke—and also, as a general rule, any

other risks considered to have an incidence exceeding 1%. Local institutional rates should be quoted whenever possible and ongoing audit should ensure that these are accurate. In addition patients should be provided with appropriate information in relation to any potential complications about which they specifically ask.

Process of obtaining consent for follow-on intervention

ELECTIVE CASES

At the initial outpatient consultation, after a discussion of the risks and benefits of the planned procedure we ask patients to sign the generic hospital consent form. This document contains no procedure specific information and has little legal standing. Accordingly, we also issue the patient with an additional information/consent form that includes risks calculated from our own data expressed as both odds and percentages, as well as further information about balloon angioplasty and stenting. The layout and content is based on similar documents borrowed from other institutions and is constantly revised to keep it up to date with changes in practice. The patient takes this home and brings it back to a nurse led preadmission clinic one week before the procedure. This clinic has patient education as its major goal. The procedures are discussed again in a group setting (usually 6–8 patients per group) and then patients are reviewed individually by the rotating cardiology senior house officer (SHO) working with the particular consultant. One week later, immediately before the procedure, patients are reviewed by the consultant and given a final opportunity to ask questions before being asked to sign the information/consent proforma.

URGENT/EMERGENCY CASES

Depending on the condition of the patient, the above process which takes place over several weeks to months may have to be condensed into 1–2 days (high risk unstable angina), 1–2 hours (rescue angioplasty), or 20–30 minutes (primary angioplasty). In the worst case of cardiogenic shock with associated cerebral hypoperfusion it may be very difficult to obtain truly informed consent from the patient. In this situation, if the patient is considered to be neurologically incompetent then the law allows emergency medical treatment to be administered without consent. As always, but particularly in these high risk cases, it is important to maintain good communication with the next of kin and we try to ensure that a senior member of medical staff briefs the family before the patient is taken to the catheterisation laboratory. We do not have separate information/consent forms for each of the above clinical scenarios and there will clearly be a variable additional risk of death and myocardial infarction compared to the figures quoted for elective cases. In addition, the magnitude of this additional risk depends to some extent on factors such as lesion morphology and will not be known until the diagnostic procedure has been performed. The cardiologist who elects to proceed in any given case does so in the

expectation that such additional risks will be offset by the benefit of immediate revascularisation. Clearly individual operator experience is a crucial factor in informing this process, particularly as most patients leave the decision to proceed or otherwise with the doctor.

Other issues relevant to performing follow-on intervention

SCHEDULING IN THE CATHETERISATION LABORATORY

Unplanned coronary intervention can easily disrupt a busy list and result in late finishes and cancelled cases. As such it is sometimes not possible to proceed, particularly in the case of patients requiring multivessel intervention. We always advise patients that time constraints may not allow a follow-on procedure but are nevertheless able to proceed in approximately 80% of elective diagnostic cases requiring PCI. Patients in whom this is not possible often express disappointment but are given the next available admission date before going home. One of the major advantages of follow-on PCI is that it minimises overall waiting time and so, in our hospital, patients who require a second procedure rarely wait more than 4–6 weeks. Undoubtedly, the presence of two or more catheterisation laboratories in any centre potentially reduces the disruption caused by follow-on PCI, assuming of course that more than one trained operator is available at any given time.

IMPACT ON BED REQUIREMENTS

Beds to allow patients undergoing unplanned PCI to stay overnight may often not be available. Same day discharge has been shown to be safe in uncomplicated PCI performed in the morning, and this practice may be facilitated by groin closure devices and/or the use of the radial artery for access. However, it is difficult to perform day case PCI if the procedure has been performed in the afternoon, and impossible if the patient has received a platelet glycoprotein IIb/IIIa inhibitor. Accordingly a successful follow-on intervention programme requires ring fenced beds staffed overnight and protected from use by general medical/cardiological admissions. Ideally these beds should be staffed by nurses rotating through the coronary care unit and the catheterisation laboratories.

ANTIPLATELET TREATMENT

In planned PCI we routinely initiate treatment with clopidogrel at the pre-admission clinic one week before the procedure. In patients undergoing their first diagnostic procedure, selected patients thought likely to proceed to PCI are pretreated in the same way. If any of the remaining patients proceed to PCI they receive 300 mg clopidogrel at the time of the procedure, as do urgent and emergency cases. It might be preferable to pretreat all patients undergoing elective PCI for a week, but our selective policy avoids pretreating everyone undergoing angiography and in our experience has not been associated with any problems.

HIGH RISK ELECTIVE PCI

Preprinted consent documents quote risks for the average population undergoing elective PCI. The risk in an individual patient may be significantly higher—for example, in the extreme case of unprotected left main stem stenosis with severe heart failure. Such cases are not suitable

for follow-on PCI and, if turned down for surgery because of comorbidity, the patient needs to be counselled again and re-consented emphasising the higher risk. More difficult is the example of single vessel disease in a large left anterior descending artery with either an ostial stenosis or involvement of a large diagonal branch. A decision to follow-on in this situation depends largely on whether the operator believes that the technical complexity of the lesion(s) increases the risks of the case significantly above that previously discussed with the patient. If that is the case, the consent is not valid and a follow-on procedure should not be performed. Sometimes the patient may return to the ward with the arterial sheath in place for further discussion involving, if appropriate, the next of kin. If the patient decides to go ahead, they can be re-consented and the case can usually be added on to the end of the list.

SURGICAL COVER

It is not routine practice in the UK to discuss all patients undergoing PCI with a cardiac surgeon and we do not do so before follow-on PCI. Emergency bypass surgery for failed angioplasty is now almost of historical interest only, but nevertheless we continue to include it in our consent proforma. As our cardiac surgical cover is off-site, the proforma also states that if emergency surgery is required this would necessitate an emergency ambulance transfer to a cardiac surgical centre.

Summary

We have described one method of obtaining informed consent and preparing patients for follow-on intervention. There is considerable variation between centres in both the process of obtaining consent and the content of any written material provided to patients. As computerised audit and reporting systems develop it should be possible to construct risk adjusted minimum standards for complication rates for a range of coronary interventions conducted in a variety of clinical settings and to include local rates and outcomes in consent forms. In the era of risk management and clinical governance, and against a background of increasing complaints and litigation, there is also a clear need to consider the introduction of nationally agreed pre-printed, procedure specific consent documentation for all PCIs whether performed as follow-on procedures or not.

ANDREW DOCHERTY
KEITH G OLDROYD

Lanarkshire Cardiac Catheterisation Laboratories,
Hairmyres Hospital,
East Kilbride,
Glasgow G75 8RG, UK
keith.oldroyd@laht.scot.nhs.uk

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